510(k)
Summary
Multichem IA
Plus

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k132091

1.0 Submitter

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SEP 20 2013

Submitter Contact

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2.0 Date Submitted

August 16, 2013

3.0 Device Identification

3.1	Proprietary Names:	Multichem IA Plus
3.2	Common Name:	Multi-Analyte Control, All Kinds (Assayed and Unassayed)
3.3	Classification:	Class 1, Reserved
3.4	Product Code:	JJY
3.5	Regulation Number:	21 CFR 862.1660

4.0 Legally Marketed Predicate Device

Candidate	Predicate	Manufacturer	Document Number
Multichem IA Plus	Liquichek™ Immunoassay Plus Control	Bio-Rad Laboratories	k001373

The Multichem IA Plus control is substantially equivalent to the previously cleared Bio-Rad product listed above, currently in commercial distribution.

5.0 Device Description

The Multichem IA Plus control is prepared from human serum to which purified biochemical material (extracts of human and animal origin), chemicals, drugs, preservatives and stabilizers have been added. The control is used in liquid form for convenience.

Three levels of control are available to allow performance monitoring within the analytical range. Multichem IA Plus Level 1, Level 2 and Level 3 controls are available in tri-level and single level kit configurations. Individual analyte values listed in the package insert are specific for the instrument system utilized.
Below are the different kit configurations:
Multichem IA Plus
Model 05P76-10 with Tri-Level controls; 4 vials of each level with 5 mL contents
Model IA310A with Tri-Level controls; 4 vials of each level with 5 mL contents
Model IA311A with Level 1 control; 12 vials with 5 mL contents
Model IA312A with Level 2 control; 12 vials with 5 mL contents
Model IA313A with Level 3 control; 12 vials with 5 mL contents

All human source material was tested and found negative by FDA approved methods for HBSAg, HCV and HIV-1/2.

6.0 Intended Use

Multichem IA Plus control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are listed in the package insert:

Alpha Fetoprotein (AFP)
Anti-thyroglobulin
Anti-thyroperoxidase
BNP
CA 125
CA 15-3
CA 19-9
Carbamazepine
Carcinogenic Embryonic Antigen (CEA)
CK-MB
Cortisol
C-Peptide
DHEA Sulfate
Digoxin
Estradiol
Ferritin
Folate
Follicle Stimulating Hormone (FSH)
Gentamicin
Homocysteine
Human Chorionic Gonadotropin (BhCG)
Immunoglobulin E
Insulin
Luteinizing Hormone
Myoglobin
Phenobarbital
Phenytoin
Progesterone
Prolactin
Prostate Specific Antigen, Total
Prostate Specific Antigen, Free
Parathyroid Hormone (PTH) (1-84)
Sex Hormone Binding Globulin (SHBG)
Triiodothyronine, Free (FT3)
Triiodothyronine, Total (TT3)
T-Uptake
Thyroxine, Free (FT4)
Thyroxine, Total (TT4)
Testosterone
Theophylline
Thyroid Stimulating Hormone (TSH)
Troponin I
Valproic Acid
Vancomycin
Vitamin B_{12}
25-OH Vitamin D

7.0 Comparison to the Predicate

Multichem IA Plus control claims to be substantially equivalent to the Liquichek™ Immunoassay Plus control. The controls have same / similar design and modes of operation. The key features are summarized in the table on the following page.

Characteristics	Predicate Device: Liquichek™ Immunoassay Plus Control	Candidate Device: Multichem IA Plus Control
Similarities		
Intended Use:	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	The Multichem IA Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form:	Frozen until use Liquid	Frozen until use Liquid
Matrix:	Human serum	Human serum
Storage (Unopened)	-20° to -70°C Until expiration date	-20° to -80°C Until expiration date
Differences		
Thawed and Open	All analytes are stable for 14 days with the following exceptions: Folate will be 4 days and Estradiol will be 5 days	All analytes are stable for 10 days with the following exceptions: C-Peptide and Homocysteine will be 7 days; PTH Intact, Troponin I and 25OH Vitamin D will be 4 days; Folate will be 2 days; and BNP will be for 1 hour.
Analytes	Contains: 11-Deoxycortisol 17-Alpha Hydroxyprogesterone 25-Hydroxy Vitamin D Acetaminophen Aldosterone Alpha Fetoprotein (AFP) Amikacin Amiodarone Amitriptyline Androstenedione Angiotensin I Antithyroglobulin antibody (anti-TPO-Ab) Antithyroid Peroxidase Antibodies (anti TPO-Ab)	Contains: Alpha Fetoprotein (AFP) Anti-thyroglobulin Anti-thyroperoxidase BNP

Characteristics	Predicate Device: Liquichek™ Immunoassay Plus Control	Candidate Device: Multichem IA Plus Control
		CA 125
		CA 15-3
		CA 19-9
	Caffeine	
	Carbamazepine	Carbamazepine
	Carbamazepine, Free	
	Carcinoembryonic Antigen (CEA)	Carcinogenic Embryonic Antigen (CEA)
	Chloramphenicol	
	CK-MB Isoenzyme	CK-MB
	Cortisol	Cortisol
		C-Peptide
	Cyclosporine	
	Dehydroepiandrosterone (DHEA) (1)	
	Dehydroepiandrosterone (DHEA)(Sulfate)	DHEA Sulfate
	Desipramine	
	Digoxin	Digoxin
	Disopyramide	
	Estradiol	Estradiol
	Estriol, Free	
	Estriol Total	
	Estrogen, Total	
	Ethosuximide	
	Ferritin	Ferritin
	Flecainide	
	Folate	Folate
	Follicle Stimulating Hormone (FSH)	Follicle Stimulating Hormone (FSH)
	Fructosamine	
	Gentamicin	Gentamicin
		Homocysteine
	Human Chorionic Gonadotropin (hCG)	Human Chorionic Gonadotropin (BhCG)
	Human Chorionic Gonadotropin (hCG)-Beta Subunit	
	Human Growth Hormone (hGH)	

Characteristics	Predicate Device: Liquichek™ Immunoassay Plus Control	Candidate Device: Multichem IA Plus Control
	Ibuprofen	
	Imipramine	
	Immunoglobulin A (IgA)	
	Immunoglobulin E (IgE)	Immunoglobulin E
	Immunoglobulin G (IgG)	
	Immunoglobulin M (IgM)	
	Insulin	Insulin
	Iron	
	Lidocaine	
	Lithium	
	Luteinizing Hormone (LH)	Luteinizing Hormone
		Myoglobin
	N-Acetylprocainamide (NAPA)	
	Netilmicin	
	Nortriptyline	
	Phenobarbital	Phenobarbital
	Phenytoin	Phenytoin
	Phenytoin, Free	
	Primidone	
	Procainamide	
	Progesterone	Progesterone
	Prolactin	Prolactin
	Propanolol	
	Prostatic Acid Phosphatase (PAP)	
	Prostate Specific Antigen (PSA)	Prostate Specific Antigen, Total
	Prostatic Specific Antigen, Free (PSA, Free)	Prostate Specific Antigen, Free
	Parathyroid Hormone-MM (PTH-MM)	Parathyroid Hormone (PTH) (1-84)
	Quinidine	
	Salicylate	
	Sex Hormone Binding Globulin (SHBG)	Sex Hormone Binding Globulin (SHBG)
	Somatomedin-C	
	T3, Free	Triiodothyronine, Free (FT3)
	T3, Total	Triiodothyronine, Total (TT3)
	T3 Uptake/T Uptake	T-Uptake

Characteristics	Predicate Device: Liquichek™ Immunoassay Plus Control	Candidate Device: Multichem IA Plus Control
	T4, Free	Thyroxine, Free (FT4)
	T4, Total	Thyroxine, Total (TT4)
	Testosterone	Testosterone
	Testosterone Free	
	Theophylline	Theophylline
	Thyroglobulin	
	Thyroid Stimulating Hormone (TSH)	Thyroid Stimulating Hormone (TSH)
	Thyroxine Binding Globulin (TBG)	
	Tobramycin	
	Total Iron Binding Capacity (TIBC)	
	Tricyclic Antidepressants Screen (TCA)	
		Troponin I
	Valproic Acid	Valproic Acid
	Valproic Acid, Free	
	Vancomycin	Vancomycin
	Vitamin B_{12}	Vitamin B_{12}
		25-OH Vitamin D

8.0 Performance Characteristics

Value Assignment Summary

Value assignment testing was performed utilizing internal procedures and protocols to determine typical values that would be seen for the product across Abbott ARCHITECT i2000® and c8000® Chemistry systems with the associated reagent test systems .Value assignment ranges were established at the pre-determined criteria of 20% around the grand mean and expanded to 30%, if needed to ensure that 3SD's either side of the mean were within the established range. The values provided in the instructions for use were derived from replicate analyses and are specific for a particular lot of product. Tests were performed by the control manufacturer and/or by independent laboratories, for various methods and instrument systems. Laboratory means may vary from the values listed during the life of the control. Values are provided only as guidelines, each laboratory should establish its own statistical limits.

Stability Testing Summary

Stability studies have been performed to determine the open vial stability and shelf-life for this control. For open vial stability, Techno-path utilized internal procedures and two protocols methods. Product claims are as follows:

Open Vial Stability:

Analytes are stable for 10 days after being thawed and opened when stored tightly capped at 2°C to 8°C with the following exceptions:

- BNP will be stable for 1 hour
- C-Peptide will be stable for 7 days
- Folate will be stable for 2 days
- Homocysteine will be stable for 7 days
- Parathyroid Hormone will be stable for 4 days
- Troponin I will be stable for 4 days
- 25-OH Vitamin D will be stable for 4 days

A combination of accelerated and real-time testing was carried out utilizing CLSI EP25A in order to support a shelf-life storage claim of -20° to -80°C for 30 months. The results concluded that the Multichem IA Plus controls are predicted to be stable for 30 months when stored at -20°C to -80°C. The real-time testing is on-going.

Traceability Summary

The analytes contained within the Multichem IA Plus controls (Level, 1, 2 and 3) were obtained from commercially available sources or are endogenous to the base serum matrix. Techno-path does not claim traceability to higher order reference materials or methods.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Multichem IA Plus control is as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 20, 2013

Techno-path Manufacturing Ltd.
C/O Stephanie Garth, Consultant
Global Compliance Plus
325 Big Elm St.
HIGHLAND VILLAGE TX 75077

Re: K132091
Trade/Device Name: Multichem IA Plus
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJY
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Garth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k132091

Device Name: Multichem IA Plus

Indications for Use:

Multichem IA Plus is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are listed in the package insert:

Alpha Fetoprotein (AFP)	Folate	Sex Hormone Binding Globulin
Anti-thyroglobulin	Prostate Specific Antigen, Free	T-Uptake
Anti-thyroperoxidase	Follicle Stimulating Hormone (FSH)	Testosterone
Human Chorionic Gonadotropin (BhCG)	Triiodothyronine, Free (FT3)	Theophylline
BNP (1-32)	Thyroxine, Free (FT4)	Troponin I
CA 125	Gentamicin	Thyroid Stimulating Hormone (TSH)
CA 15-3	Homocysteine	Triiodothyronine, Total (TT3)
CA 19-9	Immunoglobulin E	Thyroxine, Total (TT4)
Carbamazepine	Insulin	Valproic Acid
Carcinogenic Embryonic Antigen (CEA)	Luteinizing Hormone	Vancomycin
CK-MB	Myoglobin	Vitamin B12
Cortisol	Parathyroid Hormone (PTH) (1-84)	25-OH Vitamin D
C-Peptide	Phenobarbital	
DHEA-Sulfate	Phenytoin	
Digoxin	Progesterone	
Estradiol	Prolactin	
Ferritin	Prostate Specific Antigen, Total	

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132091